PSJ3

Exhibit 508

CONFIDENTIAL

HDMA Political Strategy for DEA Suspicous Orders Matter

OBJECTIVE: To ensure that lawmakers receive: (1) a balanced understanding of the role of distributors play (and are able to do) in the supply chain to ensure a secure distribution of controlled substances, and (2) to inform them of additional steps the industry is taking to address the issue of prescription drug abuse.

TARGET:

- House/Senate Judiciary Committees
- House/Senate Appropriations Committee/Subcommittee
- House/Senate Leadership
- Constituent Members

TACTICS: The HDMA Hill DEA strategy will be closely aligned with our DEA regulatory strategy.

1. Complete and present *Recommended Industry Compliance Guidelines* to DEA General Counsel
   ***Status*:** Request to be made week of 3/17. The discussion and outcome of this meeting will be critical in driving all further tactics and messaging.

2. Brief House Appropriations Subcommittee members who participated in 3/12 DEA budget justification hearing. Seek questions to be asked for the record.
   ***Status*:** In development

3. Brief Senate Appropriations Subcommittee members in advance of DEA budget justification hearing. Seek commitment to ask questions of DEA Administrator.
   ***Status*:** In development

4. Meet with key House/Senate Judiciary committee members to brief them on the role of distributors.
   ***Status*:** In development

5. Meet with Scott Gottlieb, former FDA official, who recently wrote critical piece about DEA practices and impact on medicine in WSJ. Brief Dr. Gottlieb on the role of distributors and the DEA's expectations of our members.
   ***Status*:** Dr. Gottlieb has agreed to meet with HDMA.

6. Educate and seek advocates for HDMA among pain community who will assist in delivering our message to Hill

   ***Status*:** HDMA joined and briefed the Pain Care Forum, an informal coalition of pharmaceutical companies and patient advocacy groups focusing on pain management issues, and will follow up upon release of our Industry Compliance Guideline.

7. Educate and meet with the pharmacy community, i.e. NACDS, NCPA, APhA, on DEA's expectations of HDMA members and the potential impact it may have on their members.

   ***Status*:** HDMA met with the pharmacy community in February and discussions are on-going.

8. Identify high-level Congressional "champion" who will request a meeting with DEA to discuss concerns with current tactics.

   ***Status*:** In development

9. Identify and consider state-related groups/coalition which have history of working with the DEA on prescription drug related issues. As an example, the National Association of State Controlled Substances Authorities, National Association of Boards of Pharmacy

   ***Status*:** To be considered

Potential Hill Questions for DEA

1. I support your efforts to shut down rogue internet pharmacies, which I believe are contributing to the epidemic of prescription drug abuse in this country. Do you have any estimate as to how many rogue pharmacies are diverting controlled substances, either by the Internet or otherwise?

2. Isn't it true that in order to distribute, dispense, or prescribe controlled substances that the wholesale distributor, pharmacy, and physician must have a DEA registration?
    - Does DEA inspect or otherwise investigate applicants before granting them controlled substance registrations? If not, why not?
    - Is your inability to inspect these pharmacy and physician registrants a funding issue?

3. How many registrations has DEA issued for:
    - Wholesale distributors
    - Pharmacies
    - Physicians

4. How is DEA working with Boards of Pharmacies and Medicine to address the inappropriate dispensing or prescribing of controlled substances?

5. You mentioned that DEA suspended the registrations of 7 wholesale distributors as part of your Internet pharmacy initiative.
    - Can you tell me whether the pharmacies that these wholesale distributors were supplying had a valid DEA registration to dispense controlled substances?
    - Is evidence of a valid DEA registration and pharmacy license sufficient for a wholesaler to sell controlled substances to them?

6. Hasn't your Agency in fact told the wholesale distribution industry that they cannot rely upon the DEA registration that you have issued to these pharmacies?
    - If the wholesale distributor cannot rely upon the DEA registration your Agency has issued to their pharmacy customer, then aren't you placing the wholesaler in the position of having to determine whether the pharmacy or physician is dispensing or prescribing controlled substances appropriately?
    - Can or should a wholesale distributor be asked to determine the appropriateness of a validly-licensed pharmacy's practice of pharmacy or a validly-licensed doctor's practice of medicine?
    - What additional requirements have you placed on wholesale distributors to require them to know their customer?
    - If these pharmacies or doctors do not have DEA registration numbers, then the wholesale distributor cannot sell to them, correct?
    - If, however, you pull the registration of the wholesaler but don't take equivalent action against the pharmacy, then that rogue pharmacy can

simply switch to another one of the approximately 1,000 licensed wholesalers in this country and the problem is not solved. I'd ask you to consider this as you develop your strategy moving forward.

7. When your Agency pulls the registration of a wholesaler, does it just affect the questionable pharmacies serviced by that wholesaler, or does it prevent that wholesaler from providing controlled substances to all of its customers?
    - I am concerned that by pulling the registration for all of its customers, the wholesaler is prevented from servicing their legitimate customers and this could have a significant impact on patient access to critical medicines. Why not simply require the wholesaler to stop shipments to the problematic pharmacy?
    - Isn't your initiative overly broad and not focused specifically enough on the rogue pharmacies, which in fact would make up a miniscule percentage of any legitimate wholesaler's business?

8. Clearly, if a customer is known to be diverting prescription drugs and the wholesale distributor continues to supply that customer, a violation of their registrant responsibilities has occurred. But my concern here is that your expectations go to a much higher level, asking the wholesaler to in essence be your investigator. I don't think that's appropriate. It seems to me at the end of the day, this prescription drug abuse is caused by inappropriate prescribing and inappropriate dispensing, neither of which wholesalers are authorized or capable of regulating or enforcing.

9. It is my understanding that distributors report data to the DEA through the ARCOS database. What does DEA do with this information?